K000704

MAY 1 9 2000

510(k) Summary

Company: DMC medical limited
Unit 9 Distribution Centre
Shannon Free Trade Zone
Shannon, County Clare, Ireland

Tradename: DMC Saphenous Vein Distention System

Classification: Class II

Description: The DMC Saphenous Vein Distention System is comprised of four biocompatible components including a polypropylene syringe, a polycarbonate two-way stopcock, a medical grade silicone pressure limiting balloon, and polycarbonate irrigation cannulas. The components are stored in a vein storage tray which is placed inside a primary tray.

The device is used to for the distention and irrigation of the saphenous vein which is being tested prior to use as a coronary or peripheral bypass graft. The SVDS-200—limits the nominal pressure to 200 mg Hg. The SVDS-300—limits the nominal pressure to 300 mg Hg. The SVDS-400—limits the nominal pressure to 400 mg Hg.

Material: The syringe, stopcock, and cannulas are made from polycarbonates, and the balloon is made from silicone rubber.

Indications: The DMC Saphenous Vein Distention System is indicated for use in the distention and irrigation of the saphenous vein which is being tested prior to use as a coronary or peripheral bypass graft.

Performance Data: In a review article by Bonchek, LI, in "Prevention of endothelial damage during preparation of saphenous veins for bypass grafting", J Thorac Cardiovasc Surg 79;911-915, 1980, the author states that because of the potential late consequences of early endothelial damage to vein grafts, distention of veins before grafting to overcome spasm and to identify leaks must be done at controlled pressures.

Substantial Equivalence: The device is substantially equivalent to the Bonchek Vein Distention System by Shiley, Inc. (currently Sorin Biomedica , Irvine, California), per K792134 cleared on December 4, 1979.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2000

Ms. Charmain Henderson
Director of Regulatory Affairs
DMC medical limited
511 Catalina Road
Fullerton, CA 92835

Re: K000704
DMC Saphenous Vein Distention System (SVDS)
Regulatory Class: II
Product Code: 79 GBX
Dated: February 25, 2000
Received: March 2, 2000

Dear Ms. Henderson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division Of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000704

Device Name: DMC Saphenous Vein Distension System

Indications For Use: The Saphenous Vein Distension System is indicated for use in patients undergoing heart surgery where the saphenous vein is required as a coronary bypass graft. The system is used to distend the vein, to facilitate ligating side branches in the vein.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000704

(Optional Format 3-10-98)